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PTO/SB/21 (01-03)
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TRANSMITTAL	Application Number	10/666,364
TRANSMITTAL	Filing Date	09/19/2003
FORM	First Named Inventor	Robert S. Galen
(to be used for all correspondence after initial filing)	Art Unit	1743
	Examiner Name	unknown
Total Number of Pages in This Submission 10	Attorney Docket Number	DDI-028CON1
E	NCLOSURES (Check all tha	t apply)
Fee Transmittal Form	Drawing(s) Licensing-related Papers	After Allowance Communication to Group Appeal Communication to Board
Fee Attached Amendment/Reply	Petition	of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
After Final	Petition to Convert to a Provisional Application	Proprietary Information
Affidavits/declaration(s)	Power of Attorney, Revocation Change of Correspondence Addr	ess Status Letter
Extension of Time Request	Terminal Disclaimer	Other Enclosure(s):
Express Abandonment Request	Request for Refund	Statement under CFR 1.97
Information Disclosure Statement	CD, Number of CD(s)	
Certified Copy of Priority Document(s)	·	
Response to Missing Parts/ Incomplete Application		
Response to Missing Parts under 37 CFR 1.52 or 1.53		
SIGNATUR	E OF APPLICANT, ATTORN	EY, OR AGENT
Mayumi Maeda Reg. No. 40,0° ndividual	75	·
Signature		
Date /3/4/2004		
CERTI	FICATE OF TRANSMISSION	//MAILING
hereby certify that this correspondence is being facsimile irst class mail in an envelope addressed to: Commissione	e transmitted to the USPTO or deposited wer for Patents, Washington, DC 20231 on t	ith the United States Postal Service with sufficient postage as his date: 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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PTO/SB/17 (10-03)

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FEE	TR	AN	SMIT	TAL
	for	FY	2004	

(\$) 180

Effective 10/01/2003. Patent fees are subject to annual revision.

Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

Name (Print/Type)

Mayumi Maeda

Complete if Known			
Application Number	10/666,364	-	
Filing Date	September 19, 2003		
First Named Inventor	Galen		
Examiner Name	Yelena G. Gakh		
Art Unit	1743		
Attorney Docket No.	DDI-0028CON1		

METHOD OF PAYMENT (check all that apply)	FEE CALCULATION (continued)					
Check Credit card Money Other None		DDITI	ONAL	_ FEE	:S	
Deposit Account:		ntity	Small	Entity		
Deposit Account 10-750	Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
Number	1051	130	2051	65	Surcharge - late filing fee or oath	
Deposit Account Name Johnson & Johnson	1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	<u> </u>
The Director is authorized to: (check all that apply)	1053	130	1053		Non-English specification	ļI
Charge fee(s) indicated below Credit any overpayments	1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
Charge any additional fee(s) or any underpayment of fee(s)	1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.	1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
FEE CALCULATION	1251	110	2251	55	Extension for reply within first month	
	1252	420	2252	210	Extension for reply within second month	
1. BASIC FILING FEE Large Entity Small Entity	1253	950	2253	475	Extension for reply within third month	
Fee Fee Fee Fee Fee Description Fee Paid Code (\$)	1254	1,480	2254	740	Extension for reply within fourth month	
1001 770 2001 385 Utility filing fee	1255	2,010	2255	1,005	Extension for reply within fifth month	
1002 340 2002 170 Design filing fee	1401	330	2401	165	Notice of Appeal	
1003 530 2003 265 Plant filing fee	1402	330	2402	165	Filing a brief in support of an appeal	
1004 770 2004 385 Reissue filing fee	1403	290	2403	145	Request for oral hearing	
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to institute a public use proceeding	
SUBTOTAL (1) (\$)	1452	110	2452	55	Petition to revive - unavoidable	
	1453	1,330	2453	665	Petition to revive - unintentional	
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501	1;330	2501	665	Utility issue fee (or reissue)	
Extra Claims below Fee Paid	1502	480	2502	240	Design issue fee	
Total Claims 20** = X =	1503	640	2503	320	Plant issue fee	
Claims X = X = X = Multiple Dependent	1460	130	1460	130	Petitions to the Commissioner	
	1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
Large Entity Small Entity Fee Fee Fee Fee Fee Description	1806	180	1806		Submission of Information Disclosure Stmt	180
Code (\$) Code (\$)	8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1202 18 2202 9 Claims in excess of 20	1809	770	2809	385	Filing a submission after final rejection	
1201 86 2201 43 Independent claims in excess of 3					(37 CFR 1.129(a))	
1203 290 2203 145 Multiple dependent claim, if not paid 1204 86 2204 43 ** Reissue independent claims	1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
over original patent	1801	770	2801	385	Request for Continued Examination (RCE)	
1205 18 2205 9 ** Reissue claims in excess of 20 and over original patent	1802	900	1802	900	Request for expedited examination of a design application	
SUBTOTAL (2) (\$)	Other f	ee (spe	ecify) _			
**or number previously paid, if greater; For Reissues, see above	*Reduc	ced by	Basic F	iling Fe	ee Paid SUBTOTAL (3) (\$) 180	
SUBMITTED BY (Complete (if applicable))						

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Registration No.

(Attorney/Agent)

40.075

Telephone 408 956 4790





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Robert Galen et al.

Serial No.

10/666,364

Art Unit: 1743

Filed

September 19, 2003

Examiner: Yelena G. Gakh

For

Apparatus for Combined Assay for Current Glucose Level and Intermediate

or Long-Term Glycemic Control

I hereby certify that this correspondence or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

(Name of applicant, assignee, or Registered Representative)

(Signature)

(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with the first or second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in \$1.17(p). In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in §1.17(p). M In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

\boxtimes	Copies of each of the references listed on the attached Form PTO-1449 are
enclosed here	ewith.
herewith EXO	Copies of references listed on the attached Form PTO-1449 are enclosed CEPT THAT:
	•
	In view of the voluminous nature of references, and the likelihood that
	these references are available to the Examiner in the file history of the
	parent application (Serial No. 09/477,900), copies are not enclosed herewith.
·	If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
	Copies of only foreign patent documents and non-patent literature are enclosed
in accordance	with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application
publication li	sted on the attached Form PTO-1449 are not enclosed because this U.S. patent
application w	as filed after June 30, 2003 or this international application has entered the
national stage	under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement
under 37 CFF	2 1.98 (a)(2)(i).
	There are no listed references which are not in the English language.
as follows:	The relevance of those listed references which are not in the English language is
	Attached are copies of search report(s) from corresponding patent application(s),
which are list	ed on the attached Submission Under MPEP 609 D.

Attached are the following non-published pending patent applications which
may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-
0750/DDI-0028-CON1/MM.
Respectfully submitted,
Mayumi Maeda Reg. No. 40,075 Attorney for Applicants
Johnson & Johnson

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 1 of 1

a conection of information unless it displays	a valid OMB Cortifor Humber.
Application Number	10/666,364
Filing Date	09/12/2003
First Named Inventor	Galen
Group Art Unit	1743
Examiner Name	Yelena G. Gakh
Attorney Docket Number	DDI-028CON1

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item	1
i	Cite	include it are or the author (in CAPTIOL ETTERS), the of the article (when appropriate), the of the item	T ²
Examiner's		(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	1.
Initials*	No.1	publisher, city and/or country where published	
		English Abstract of Japanese Patent JP63182567 published July 27, 1988, Applicant Isolab, Inc.	
		English Abstract of Japanese Patent JP5209836 published August 20, 1993, Applicant Terumo Corp.	
		English Abstract of Japanese Patent JP4110662 published April 13, 1992, Applicant Kiyouto Daiichi Kagaku:KK	
		English Abstract of Japanese Patent JP52131786 published November 4, 1997, Applicant Eastman Kodak Co.	
		Letter from Shusaku Yamamoto dated September 7, 2004 forwarding Japanese Office Action and Search Results.	1
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Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Robert Galen et al.

Serial No. : 10/666,364 Art Unit: 1743

Filed : September 19, 2003 Examiner: Yelena G. Gakh

For : Apparatus for Combined Assay for Current Glucose Level

and Intermediate or Long-Term Glycemic Control

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10-5- 2004 (Date of Deposit)

Jane Silarajs
(Name of applicant, assignee, or Registered Representative)

-

10-5-

5 2004 (Date of Signature)

(Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT UNDER 37 C.F.R. §1.97(e)

In accordance with 37 C.F.R. $\S1.97(e)$, certification is hereby made that:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or

No item of information contained in the Information
Disclosure Statement was cited in a communication from a foreign

patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Mayumi Maeda Reg. No. 40,075 Attorney for Applicants

Johnson & Johnson
International Patent Law Division
Attention: Philip Johnson
P.O. Box 1222
New Brunswick, NJ 08903
(408) 956-4790
DATED: (0/4/0/